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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/033,723

Applicant(s)

SHAH ET AL.

Examiner

David M. Naff

Art Unit

1651

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28,30 and 32-78 is/are pending in the application.
- 4a) Of the above claim(s) 46-66,68 and 69 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28,30,35,38,41-45, 67 and 70-78 is/are allowed.
- 6) ☒ Claim(s) 32-34, 36, 37, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1651

**DETAILED ACTION**

Claims in the application are 28, 30 and 32-78.

An amendment of 3/24/06 amended claims 67 and 74-76.

Claims 46-66, 68 and 69 stand withdrawn from further  
5 consideration pursuant to 37 CFR 1.142(b), as being drawn to a  
nonelected invention, there being no allowable generic or linking  
claim. Applicant timely traversed the restriction (election)  
requirement in the reply filed on 4/19/05.

Claims examined on the merits are 28, 30, 32-45, 67 and 70-78.

10 The text of those sections of Title 35, U.S. Code not included in  
this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 32-34, 36, 37, 39 and 40 are rejected under 35 U.S.C. 112,  
first paragraph, as failing to comply with the written description  
15 requirement. The claim(s) contains subject matter which was not  
described in the specification in such a way as to reasonably convey  
to one skilled in the relevant art that the inventor(s), at the time  
the application was filed, had possession of the claimed invention.

When requiring the active protein to be molded in a recess in a  
20 block and hardened prior to being disposed within the space of a  
sensor body as now required by amended claim 32, the specification  
supports only an invention requiring the active protein in solidified  
form to be sufficiently immobilized to minimize swelling and shrinkage  
as now required by amended claims 28 and 71. If the swelling and  
25 shrinkage are not minimized as in claims 28 and 71, molding in the

Art Unit: 1651

recess of a block of a mold as now required in claim 32 will not function as disclosed in the specification. It is suggested that claim 32 be amended as claims 28 and 71 to require sufficient immobilization to minimize swelling that would deform shape of the sensor body and shrinkage the would create voids between the active protein in solidified form and the sensor body.

***Response to Arguments***

Applicants urge that the specification provides sufficient support for operability and advantages of embodiments of the invention that relate to an active protein in solidified form, without requiring sufficient immobilization to minimize swelling and shrinkage, such as to maintain a desired shape, mechanical stability, longevity, a proper fit within the sensor body and ease of inserting the protein into the sensor body. However, when the active protein is molded in a recess in a block of a mold and hardened into a solidified form as claimed, the specification nowhere indicates that minimizing swelling and shrinkage as in claims 28 and 71 is intended to be omitted. The specification indicates that desired shape, mechanical stability, longevity, a proper fit within the sensor body and ease of inserting the protein are to be obtained together in combination with minimizing swelling and shrinkage as in claims 28 and 71. There is no disclosure supporting that minimizing swelling and shrinkage as in claims 28 and 71, desired shape, mechanical stability, longevity, a proper fit within the sensor body and ease of inserting the protein are each be separately obtained without obtaining any of the other advantages.

Art Unit: 1651

When setting forth advantages of the invention on pages 5 and 6, the specification recites advantage of "embodiments". This indicates that the advantages disclosed are to be obtained together in all embodiments, and not to have a separate embodiment for each advantage listed. There is insufficient basis in the specification that the invention provides an embodiment of minimizing swelling and shrinkage as in claims 28 and 71, and another embodiment of not minimizing swelling and shrinkage as in claim 32. If the active protein in solidified form swells and deforms the sensor body or undergoes shrinkage to create voids between the solidified active protein and the sensor body, the specification indicates the sensor will not function properly. While original claims did not require the active protein to be sufficiently immobilized to minimize swelling and shrinkage as in claim 28 and 71, these claims also did not require active protein to be molded in a recess in a block of a mold and hardened into a solidified form. When hardening in a recess in a block of a mold, the specification fails to support two embodiments as claimed, i.e. one of minimizing swelling and shrinkage as in claims 28 and 71, and another embodiment where such minimizing of swelling and shrinkage is not obtained as in claim 32.

### **Conclusion**

Claims 28, 30, 35, 38, 41-45, 67 and 70-78 are allowable.

Claims 32-34, 36, 37, 39 and 40 are free of the prior art.

This application contains claims 46-66, 68 and 69 drawn to an invention nonelected with traverse in Paper No. 4/19/05. A complete

Art Unit: 1651

reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5        A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the  
10        shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX  
MONTHS from the mailing date of this final action.

15        Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

      If attempts to reach the examiner by telephone are unsuccessful,  
20        the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN

6/9/06